K082478

510(k) Summary

[As described in 21 CFR 807.92]

MAR 9 2009

Submitted by:

Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Contact Person:

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Date Prepared:

August 22, 2008

Trade Name:

CardioPerfect Workstation Software (CPWS) Version 1.6.2

Common Name:

Medical Device Software for interpretive and stress testing electrocardiographs and diagnostic spirometry.

Classification Reference:

Class II, Diagnostic Spirometer (21 CFR 868.1840, Product Code BZG) and Cardiovascular (Product Code LOS).

Predicate Device:

CardioPerfect Workstation Software Version 1.5.0 (K052158)

Description of the Device:

CardioPerfect Workstation software is used to create a computer platform on which ECG, ABP, & Spirometry applications can operate within inherent capabilities of an off-the-shelf desktop or laptop personal computer utilizing a Windows operating system.

Intended Use:

The CardioPerfect Workstation software and associated accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic signals, as identified below, for the purpose of assisting the clinician in the diagnosis and monitoring of various diseases and/or treatment regimens. The CardioPerfect Workstation software also provides non-diagnostic functions such as patient management, data security, search tools for patient and/or test records and support for exporting data to Electronic Medical Record systems.

The CardioPerfect Workstation and associated accessories are intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients, subject to any specific contraindications identified below.

Stress Electrocardiograph – Intended Use

Using the optional ECG module and associated accessories the user can acquire, view, store and print ECG waveforms.

Resting Electrocardiograph – Intended Use

The same as defined for stress ECG plus the ability to use optional algorithms (MEANS) to generate measurements, data presentations, graphical presentations and interpretive statements on an advisory basis. These are presented for review and interpretation by the clinician.

Spirometry – Intended Use

Using the optional spirometry module and associated accessories to acquire, view, store and print measures and waveforms of pulmonary function. The spirometer should only be used with patients able to understand the instructions for performing the test.

Ambulatory Blood Pressure – Intended Use

Using the optional ABP module and associated accessories the user can acquire, retrieve, view, store and print patient ambulatory blood pressure history.

Indications for Use:

Electrocardiograph – Indications for Use

Indications for electrocardiography range from routine screening of cardiac health in the physician office environment to directed diagnostic differentiation in a hospital cardiology department.

Spirometry – Indications for Use

Indications for spirometry include, but are not limited to, the following:

- Shortness of breath
- Chronic cough
- Occupational exposure to dust or chemicals
- Assist in the diagnosis of Bronchitis
- Assist in the diagnosis of Asthma
- Wheezing
- Assist in the monitoring of bronchodilator

Ambulatory Blood Pressure – Indications for Use

Indications for ambulatory blood pressure measurement (as listed in Journal of Hypertension 2003, 21 :821-848, E. O'Brien et. at.) include, but are not limited to, the following:

- suspected "white coat" hypertension
- Suspected nocturnal hypertension
- To establish dipper status
- Resistant hypertension
- Elderly patient
- To monitor antihypertensive drug treatment
- Type 1 diabetes
- Hypertension of pregnancy
- Evaluations of hypotension
- Autonomic failure
- Masked hypertension

Technological Characteristics:

The Welch Allyn Electrocardiography and Spirometry Products are intended for use by trained operators in healthcare facilities.

The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

The optional spirometry module is indicated for use in clinical situation to assess a patient's pulmonary health status and evaluate symptoms, signs, or abnormal laboratory test results.

The CPWS version 1.6.2 is substantially equivalent to the previously released CPWS version 1.5.0 (K052158). The major difference being the change to intended use. This submission intends to change the indications for use to include interpretive ECG software for the pediatric population. The previously marketed CPWS version 1.5.0 (K052158) did not provide interpretive software support for patients less than 16 years of age. The Pediatric Modular ECG PEDMEANS Interpretive ECG algorithm developed by P. Rijnbeek, 2007, in Analysis System thesis entitled 'Automatic Interpretation of Pediatric Electrocardiograms', Erasmus University Rotterdam. This PEDMEANS algorithm, is also used in our CP 100™ and CP 200™ ECG device cleared under K072449.

Summary of Effectiveness:

The Welch Allyn CPWS team has determined that the software "Level of Concern" is Moderate. (See section 10 for CPWS software Level of Concern)

The implementation of the PEDMEANS interpretive software in the CPWS 1.6.2 electrocardiograph device, and its performance, is equivalent in every respect to the implementation of this software in the CP 100™ and CP 200™ submitted to the agency by Welch Allyn and cleared per K072449.

The MEANS algorithms were verified and found to be consistent with the requirements of IEC 60601-2-51:2003, particular requirements for safety, including essential performance, of recording and analyzing single channel and multi-channel electrocardiographs.

All requirements of the recognized and applicable standards are in compliance: EC11 (AAMI/ANSI), UL 60601-1, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4 and IEC 60601-2-25.

Additionally, risk management (risk, SFMEA and safety analysis) activities have been conducted in accordance with ISO 14971 Medical Devices – Application of risk management to medical devices and comply with IEC 60601-1-4 Medical Electrical Equipment Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2009

Welch Allyn, Inc.
c/o Mr. John Sawyer
Vice President QA/RA
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Re: K082478
Trade/Device Name: Welch Allyn CardioPerfect Workstation Software (CPWS), Version 1.6.2
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II (Two)
Product Code: BZG
Dated: February 4, 2009
Received: March 5, 2009

Dear Mr. Sawyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K082478

Device Name: Welch Allyn CardioPerfect Workstation Software (CPWS) V 1.6.2

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for B Zuckerman

(Division Sign-Off) 3/9/09

Division of Cardiovascular Devices

510(k) Number K082478

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- Evaluations of hypotension
- Autonomic failure
- Masked hypertension

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 3/9/09
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